Revision to the
Occupational Exposure to
Hazardous Chemicals in Laboratories Standard
Supporting Statement

The Standards Improvement Project–Phase III (SIP-III) is the third in a series of rulemaking actions to improve and streamline OSHA standards. The Standard Improvement Projects remove and revise individual requirements in standards that are confusing, outdated, duplicative or inconsistent. In May 2011, OSHA published the SIP-III final rule.

The SIP-III final rule removed from 25 of OSHA's substance-specific standards (see 29 CFR 1910, subpart Z) the requirements for employers to transfer employee exposure-monitoring and medical records to the National Institute for Occupational Safety and Health (NIOSH), and to notify NIOSH prior to disposal of such records. As a result of removing these transfer and notification requirements, OSHA is revising the 25 corresponding Information Collection Requests (ICRs)[1] to reduce the burden-hour and cost estimates associated with these provisions.

Edits to this supporting statement consists of strikethroughs and highlighted yellow text. These edits indicate removal of the requirement for employers to transfer records to NIOSH. Language deleted from this Supporting Statement is struck-through. Language added to the supporting statement appears highlighted in yellow.

1 ?The section of the preamble in the final SIP-III rule titled, *Office of Management and Budget Review Under the Paperwork Reduction Act of 1995* lists the 27 ICRs being revised. The 27 ICRs are being revised as follows: 23 ICRs are revised as a result of removing the requirements for employers to transfer records to NIOSH; two ICRs are being revised to remove both the requirements for employers to transfer records to NIOSH and for employers to prepare training certifications; and, two additional ICRs are being revised to remove only training certifications.

SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS OF THE STANDARD ENTITLED "OCCUPATIONAL EXPOSURE TO HAZARDOUS CHEMICALS IN LABORATORIES" (29 CFR 1910.1450)[2] (OMB CONTROL NO. 1218-0131 (May 2011))

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The main purpose of the Occupational Safety and Health Act ("OSH Act" or "Act") is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" (29 U.S.C. 651). To achieve this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health standards" (29 U.S.C. 651). The Act states further that "[t]he Secretary . . . shall prescribe such rules and regulations as [he/she] may deem necessary to carry out [his/her] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (29 U.S.C. 651).

To protect employee health, the OSH Act authorizes the Occupational Safety and Health Administration ("OSHA" or "Agency") to develop standards that provide for "monitoring or measuring employee exposure" to occupational hazards and "prescribe the type and frequency of medical examinations and other tests which shall be made available [by the employer] to employees exposed to such hazards . . . to most effectively determine whether the health of such employees is adversely affected by such exposure" (29 U.S.C. 655). Moreover, the Act directs OSHA to "issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or other harmful physical agents which are required to be monitored and measured . . . " (29 U.S.C. 657). In addition, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to the Secretary [of Labor] . . . such records regarding [the employer's] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act . . . " (29 U.S.C. 657).

The Act authorizes the Agency to issue standards that "prescribe use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure" (29 U.S.C. 655). Additionally,

2 [?]The purpose of this Supporting Statement is to analyze and describe the burden hours and costs associated with the provisions of this standard that contain paperwork requirements; this Supporting Statement does not provide information or guidance on how to comply with, or how to enforce, the standard.

the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to
the Secretary . . . such records . . . as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act . . . " (29 U.S.C. 657).

Beginning in the early 1970s, OSHA published numerous health standards to control employee exposure to toxic substances in 29 CFR part 1910, subpart Z (the "subpart Z standards").[3] However, OSHA developed the subpart Z standards primarily to protect employees exposed to toxic substances during industrial operations. These operations typically involve exposure to a few toxic substances emitted during a standardized and continuous or repetitive process that uses large quantities of the toxic substances. In laboratories, employees use small quantities of numerous hazardous chemicals[4] in a variety of analytic and clinical procedures and operations, each of which they perform infrequently or periodically. In addition, standard laboratory practices often require techniques that control the release of, and exposure to, hazardous chemicals (e.g., extensive labeling, sealed containers, protective clothing, fume hoods).[5] Moreover, laboratory employees have better knowledge of the hazardous chemicals with which they work than do employees involved in typical industrial operations; based on the high level of training they receive, laboratory employees usually have a thorough understanding of the chemical properties of these substances, as well as the safety and health problems associated with them.

Based on this evidence, OSHA concluded that, in general, laboratory employees have minimal exposures to hazardous chemicals in the workplace (i.e., below the action level (i.e., "AL") or, in the absence of an AL, the permissible exposure limit ("PEL") specified by subpart Z for any of these substances). Therefore, under the authority granted by the OSH Act, the Agency published a health standard governing occupational exposure to hazardous chemicals in laboratories (29 CFR 1910.1450; the "Standard").

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the Agency has made of the information received from the current collection.

The Standard contains a number of paperwork requirements. The following paragraphs describe these requirements, specify who uses them, and what purpose they serve.

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3 [?]Employers also have an obligation to protect employees from exposure to toxic substances under the general-duty clause of the Act at 29 U.S.C. 654.

4 [?]For the purposes of this Supporting Statement, the term "hazardous chemical" means a chemical for which acute or chronic health effects may occur in exposed employees as demonstrated by statistically significant evidence based upon at least one study conducted in accordance with established scientific principles. (See paragraph (b) of
§ 1910.1450).

5 [?]Employers institute these practices not only to protect their employees from exposure to the toxic substances, but also to ensure the reliability of the analytic or clinical results.

A. Employee exposure determination (§1910.1450(d))

Initial monitoring (§1910.1450(d)(1))

The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

Purpose: Initial monitoring assists employers in identifying procedures and operations that require modification to reduce exposures to the AL or PEL specified by the appropriate subpart Z standard. In this regard, initial monitoring results enable employers to determine the need for engineering controls, institute new (or modify existing) work practices, and select appropriate respiratory protection to prevent employee overexposure. This information also determines whether or not the employer must perform periodic monitoring.

Periodic monitoring (§1910.1450(d)(2))

§1910.1450(d)(2) - If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

Purpose: Employers use periodic monitoring results to evaluate the effectiveness of selected control methods. In addition, these measurements remind both the employer and employees of the need to protect employees against the effects of overexposure to hazardous chemicals in laboratory facilities. These monitoring data will also inform the examining physician of the existence and extent of an employee's exposure to the hazardous chemical(s) for use in assessing the employee's medical condition.

Termination of monitoring (§1910.1450(d)(3))

Monitoring may be terminated in accordance with the relevant standard.

Employee notification of monitoring results (§1910.1450(d)(4))

The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting the results in an appropriate location that is accessible to employees.

Purpose: Notification provides employees with information they can use to assess the effectiveness of the controls their employer implement to reduce their exposures to hazardous laboratory chemicals, and to determine if any medical signs and symptoms they may be experiencing could be the result of their exposure to these chemicals.

B. Chemical Hygiene Plan (CHP) (§1910.1450(e))

§1910.1450(e)(1) - Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

§1910.1450(e)(1)(i) - Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory, and

§1910.1450(e)(1)(ii) - Capable of keeping exposures below the limits specified in paragraph (c) of this section.

§1910.1450(e)(3) - The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection:

§1910.1450(e)(3)(i) - Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

§1910.1450(e)(3)(ii) - Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

§1910.1450(e)(3)(iii) - A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

§1910.1450(e)(3)(iv) - Provisions for employee information and training as prescribed in paragraph (f) of this section;

§1910.1450(e)(3)(v) - The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

§1910.1450(e)(3)(vi) - Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

§1910.1450(e)(3)(vii) - Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer, and, if appropriate, establishment of a Chemical Hygiene Committee; and

§1910.1450(e)(3)(viii) - Provisions for additional employee protection for work with particularly

hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following provisions which shall be included where appropriate:

§1910.1450(e)(3)(viii)(A) - Establishment of a designated area;

§1910.1450(e)(3)(viii)(B) - Use of containment devices such as fume hoods or glove boxes;

§1910.1450(e)(3)(viii)(C) - Procedures for safe removal of contaminated waste; and

§1910.1450(e)(3)(viii)(D) - Decontamination procedures.

§1910.1450(e)(4) - The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

Purpose: This requirement commits employers to evaluate employee exposures to hazardous laboratory chemicals and establish an organized and complete program for reducing these exposures to the PEL specified for these chemicals. The requirement to review and update the CHP ensures that employers continue to evaluate workplace conditions, including hazardous-chemical exposures, and to implement the controls required to reduce employee overexposures. Employers are required to develop a written Chemical Hygiene Plan and ensure that they carry out the provisions.

C. Employee Information and Training (§1910.1450(f))

§1910.1450(f)(1) - The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

§1910.1450(f)(2) - Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

§1910.1450(f)(3) - Employees shall be informed of:

§1910.1450(f)(3)(i) - The contents of this standard and its appendices which shall be made available to them;

§1910.1450(f)(3)(ii) - the location and availability of the employer's Chemical Hygiene Plan;

§1910.1450(f)(3)(iii) - The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;

§1910.1450(f)(3)(iv) - Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and

§1910.1450(f)(3)(v) - The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets, (MSDSs) received from the chemical supplier.

Training (§1910.1450(f)(4))

§1910.1450(f)(4)(i) - Employee training shall include:

> §1910.1450(f)(4)(i)(A) - Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);
>
> §1910.1450(f)(4)(i)(B) - The physical and health hazards of chemicals in the work area; and
>
> §1910.1450(f)(4)(i)(C) - The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

§1910.1450(f)(4)(ii) - The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

Purpose: This requirement is essential to inform employees of the health hazards resulting from hazardous chemical exposure and to provide them with the understanding necessary to minimize these hazards. Training serves to explain and reinforce the information presented to employees on signs, labels, and MSDSs; however, this information will be effective only if employees understand the information and can take the actions necessary to avoid or minimize hazardous chemical exposure. Training also enables employees to recognize operations and locations associated with hazardous chemical exposures, thereby permitting them to limit exposure from these sources.

D. Medical Consultation and Medical Examinations (§1910.1450(g))

General (§1910.1450(g)(1) and (g)(2))

§1910.1450(g)(1) - The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:

§1910.1450(g)(1)(i) - Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

§1910.1450(g)(1)(ii) - Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.

§1910.1450(g)(1)(iii) - Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.

§1910.1450(g)(2) - All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

Purpose: The requirements specified by these paragraphs prevent the development of serious illnesses among employees overexposed or potentially overexposed to hazardous chemicals used in their work areas.

Information provided to the physician (§1910.1450(g)(3))

The employer shall provide the following information to the physician:

§1910.1450(g)(3)(i) - The identity of the hazardous chemical(s) to which the employee may have been exposed;

§1910.1450(g)(3)(ii) - A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and

§1910.1450(g)(3)(iii) - A description of the signs and symptoms of exposure that the employee is experiencing, if any.

Purpose: The examining physicians are provided this information to assist them in evaluating the employee's health and fitness for specific job assignments involving hazardous chemical exposure. The physician also uses this information to determine if an observed health condition is contributed to occupational exposure to hazardous chemicals in the laboratory work area.

Physician's written opinion (§1910.1450(g)(4))

§1910.1450(g)(4)(i) - For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:

§1910.1450(g)(4)(i)(A) - Any recommendation for further medical follow-up;

§1910.1450(g)(4)(i)(B) - The results of the medical examination and any associated tests;

§1910.1450(g)(4)(i)(C) - Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous workplace; and

§1910.1450(g)(4)(i)(D) - A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

§1910.1450(g)(4)(ii) - The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.

Purpose: The purpose of requiring the employer to obtain a physician's written opinion is to provide the employer with medical information on whether or not the employee has a condition indicating overexposure to hazardous chemicals. If such a condition exists, the employer can implement additional controls to prevent overexposure. The information also allows the employer to plan necessary medical follow-up and treatment. The requirement that the physician's opinion be in writing ensures that the information is available for future reference. Employees are given a copy of the physician's written opinion to determine the need for treatments and other interventions. The written opinion allows the physician to make recommendations to remove the employee from the contaminated area or to make recommendations for control measures.

E. Hazard Identification (§1910.1450(h))

§1910.1450(h)(1) - With respect to labels and material safety data sheets:

§1910.1450(h)(1)(i) - Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.

§1910.1450(h)(1)(ii) - Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.

§1910.1450(h)(2) - The following provisions shall apply to chemical substances developed in the laboratory:

§1910.1450(h)(2)(i) - If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.

§1910.1450(h)(2)(ii) - If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.

§1910.1450(h)(2)(iii) - If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.

Purpose: The provision ensures that employees, whether in a laboratory facility or at a downstream facility, receive adequate notice and, if necessary, other information regarding chemicals that are hazardous or potentially hazardous.

OSHA believes that this provision protects employees by alerting them to potential hazardous chemical exposures, thereby allowing them to take appropriate actions to control these exposures. In addition, this provision supplements the information and training requirements contained in paragraph (f) of the Standard.

F. Use of Respirators (§1910.1450(i))

Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.

Purpose: The purpose of this requirement is to ensure that employers and employees select, use, and maintain appropriate respirators if respirators are necessary to protect employees from hazardous chemical exposures.

G. Recordkeeping (§1910.1450(j))

§1910.1450(j)(1) - The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

Purpose: This requirement provides both employers and employees with useful information.

The information alerts employers to routine overexposures to hazardous chemicals, thereby enabling them to modify controls or take other actions necessary to reduce these exposures. The exposure monitoring and medical information contained in these records assists employees and their physicians in determining the need for, and effectiveness of, medical treatment and other interventions implemented in response to the employees' exposure to hazardous chemicals in a laboratory facility.

§1910.1450(j)(2) - The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.1020.

Purpose: Employees and their designated representatives may use these records to evaluate employee medical status over the course of employment, to determine the effectiveness of the employer's exposure reduction program, and for other reasons. An OSHA compliance officer reviews the records to assess the employer's compliance with the medical and exposure control provisions of the Standard.

Paragraph (h) of § 1910.1020 requires employers who cease to do business to transfer medical and exposure-monitoring records to the successor employer, who then must receive and maintain the records. If no successor employer is available, the employer must: At least three months before ceasing business, notify current employees who have records of their right to access these records; ~~and provide the National Institute for Occupational Safety and Health (NIOSH) with written notice of the impending disposal of these records at least three months prior to such disposal. NIOSH may use these records for research purposes (e.g., assessing the medical effects of long-term exposure to hazardous chemicals); in addition, serving as a repository for medical and exposure monitoring records, it provides employees with continuous access to their records if needed for health or other reasons.~~

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Employers may use any available technology to meet the paperwork requirements specified by the Standard. The Agency wrote these provisions in performance-oriented language, i.e., in terms of <u>what</u> information to provide, not <u>how</u> to provide it.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The information collection requirements in the Standard are specific to each employer involved, and no other sources or agencies duplicate these requirements or can make the required information available to OSHA, i.e., the required information is available only from employers.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

The information collection requirements specified by the Standard do not have a significant impact on a substantial number of small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The Agency believes that the information collection frequencies required by the Standard are the minimum frequencies necessary to fulfill its mandate "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" as specified in the OSH Act at 29 U.S.C. 651. Accordingly, if employers do not perform the information collections required by the Standard, or delay in providing this information, employees are at risk of developing serious illnesses resulting from overexposure to hazardous chemicals used in laboratory facilities.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **Requiring respondents to report information to the agency more often than quarterly;**
- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **Requiring respondents to submit more than an original and two copies of any document;**
- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Paragraph (d)(4) of the Standard requires that employers within 15 working days after receiving the results of any exposure monitoring performed under the Standard, notify each affected employee of their in writing, either individually or by posting the results in an appropriate location. This information collection is otherwise consistent with 5 CFR 1320.5.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years, even if the collection-of-information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The SIP-III notice of proposed rulemaking (NPRM; 75 FR 38645) proposed to revoke existing collection-of-information (paperwork) requirements contained in 27 existing Information Collection Requests (ICRs) approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA-95). OSHA prepared and submitted one ICR for the SIP-III proposal to OMB for review in accordance with 44 U.S.C. 3507(d). For the SIP-III final, OSHA is submitting separate ICRs to OMB.

The NPRM proposed to remove provisions that require employers to transfer employee exposure-monitoring and medical records to NIOSH and for employers to contact NIOSH prior to disposing of such records. No comments were received opposing this revision. OSHA has removed these requirements from §1910.1020(h). Since, §1910.1450(j)(2) references §1910.1020(h), OSHA has removed the associated burden hours and costs from this ICR.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

The Agency will not provide payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

To ensure that the personal information in the medical records required by the Standard remains confidential, the Agency developed §1913.10 (“Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records’) to regulate its access to these records.

11. Provide additional justification for any question of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the

information is requested, and any steps to be taken to obtain their consent.

The paperwork requirements specified by the Standard do not involve sensitive information.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage-rate categories.**

Table 1 below presents information for the different types of laboratories covered by the Standard. For each type of laboratory, the table provides an estimate of the number of facilities that expose employees to hazardous chemicals and the number of employees so exposed.

Table 1: Number of Laboratory Facilities and Employees for Each Type of Laboratory

Type of Laboratory	**No. of Facilities**	**No. of Employees**
Industrial		
Independent testing[a]	6,213	100,679
Research and development[b]	13,000	1,000,000
Subtotals	*19,213*	*1,100,679*
Clinical		
Hospital[c]	7,356	166,867
Independent-medical[d]	5,179	134,547
Subtotals	*12,535*	*301,414*
Academic (Private)		
Post-secondary[e]	2,583	107,274
Secondary[f]	11,060	41,041
Professional and Research Institutes[g]	225	110,000
Subtotals	*13,868*	*258,315*
Totals	**45,616**	**1,660,408**

[a]Source: *County Business Patterns 2005. U.S. Department of Commerce, Bureau of the Census*. Total number of Independent Testing Laboratories (ITLs) calculated as the sum of taxable establishments (6,003 establishments, NAICS 54138) and tax-exempt establishments (210 establishments). The number of tax-exempt establishments estimated as 3.5 percent of total number of ITLs, based on data from 2002 Census. Number of Employees calculated as the sum of employees in taxable establishments (93,049 employees) and employees in tax-exempt establishments (7,630 employees). The number of employees in tax-exempt establishments estimated as 8.2 percent of total number of employees in ITLs, based on data from 2002 Census.

[b]Source: Supporting Statement for the Information Collection Requirements of the Standard Entitled "Occupational Exposure to Hazardous Chemicals in Laboratories" (29 CFR 1910.1450) [ICR 1218-0131 (2005)], based on analysis by DynCorp I&ET of *The Directory of American Research and Technology; Industrial Research Labs of the United States*; and "Survey of Industrial Research and Development," National Science Foundation/Division of Science Resources Studies. Because original sources appear to not have been updated, OSHA has no basis to revise 2005 figures.

[c]Source: Supporting Statement for the Information Collection Requirements of the Standard Entitled "Occupational Exposure to Hazardous Chemicals in Laboratories" (29 CFR 1910.1450) [ICR 1218-0131 (2005)] and Occupational Outlook Handbook, 2008-2009 ed., Bureau of Labor Statistics. Estimate of hospital-based labs derived by adjusting the 2005 ICR estimate by the percentage increase in lab employees reported in BLS.

[d]Source: County Business Patterns 2005. U.S. Department of Commerce, Bureau of the Census (NAICS 621511).

[e]Source: U.S. Department of Education, National Center for Education Statistics, Digest of Education Statistics, 2006. Table 248: Degree-granting institutions, by control and type of institution. Estimated number of employees in 2006 based on percentage change in post-secondary labs from 2005 ICR to 2006, applied to estimate of employees in 2005 ICR.

[f]Source: U.S. Department of Education, National Center for Education Statistics, Digest of Education Statistics, 2006. Table 56: Private elementary and secondary enrollment, number of schools, and average tuition, by school level, orientation, and tuition. Estimated number of employees in 2006 based on percentage change in private secondary labs from 2005 ICR to 2006, applied to estimate of employees in 2005 ICR.

[g]Source: 2001 ICR. As OSHA was unable to identify updated establishment and employment figures, estimates from previous ICR updates have been retained.

Burden Hour and Cost Determinations

The Agency determined average wage rates using average hourly earnings. For the relevant occupational categories, OSHA adjusted the mean hourly earnings from the National Compensation Survey, June 2005, Supplementary Tables. U.S. Department of Labor, Bureau of Labor Statistics, July 2006. Supplementary Table 2.1 to allow for fringe benefits, which comprise about 29.4% of total compensation in the private sector. With wages comprising 70.6% of employee compensation, the Agency multiplied wages by 1.4 (1/0.706) to derive total hourly employee compensation. Therefore, the costs of labor used in this analysis are estimates of total hourly compensation. These estimates are:

Administrative Service Manager:	$41.29
Employee	$20.21
Office Clerk	$16.95

(A) Employee exposure determination (§1910.1450(d))

Initial monitoring (§1910.1450(d)(1) and periodic monitoring (§1910.1450(d)(2) and (d)(3))

As noted above in Item 1, laboratory employees typically use small quantities of numerous hazardous chemicals in a variety of procedures and operations, each of which they perform infrequently or periodically. In addition, standard laboratory practices require techniques that control the release of, and exposure to, hazardous chemicals (e.g., extensive labeling, sealed containers, protective clothing such a gloves and goggles, laboratory hoods). Therefore, overexposure of laboratory employees to hazardous chemicals is rare. Accordingly, OSHA assumes that only a minimal need exists to conduct initial and periodic exposure monitoring (i.e., once a year per laboratory facility), and that a laboratory supervisor takes, on average, 10 minutes (.17 hour) to distribute and collect exposure-monitoring samples and mail them for analysis. Thus, the estimated burden hours and cost for these requirements each year are:

Burden hours: 45,616 facilities x .17 hour = 7,755 hours
Cost: 7,755 hours x $41.29 = $320,204

Employee notification of monitoring results (§1910.1450(d)(4))

Assuming that employers post exposure monitoring results in an appropriate location, the Agency estimates that an office clerk spends five minutes (.08 hour) developing and posting these results for each facility once a year. Therefore, the estimated annual burden hours and cost of this provision are:

Burden hours: 45,616 facilities x .08 hour = 3,649 hours
Cost: 3,649 hours x $16.95 = $61,851

(B) Chemical hygiene plan (§1910.1450(e))

This paragraph requires new laboratory facilities to develop a chemical hygiene plan (CHP), while existing facilities must review their CHPs at least annually.[6] The Agency estimates that the number of laboratory facilities increases by 750 each year, and that a laboratory supervisor (acting as the Chemical Hygiene Officer) takes 8 hours to develop a new CHP and one-half (.5) hour to update an existing CHP. The burden hour and cost estimate for this requirement are:

Burden hours: (750 new CHPs x 8 hours) + (45,616 existing CHPs x .5 hours) = 28,808 hours

6This paragraph also specifies that employers must, as appropriate, establish designated areas to provide employees with additional protection. This provision does not require employers to establish records or maintain information, so the Agency is not taking any burden for this requirement.

Costs: 28,808 hours x $41.29 = $1,189,482

(C) Employee information and training (§1910.1450(f))

The Agency assumes that 20% (332,082) of the employees covered by the Standard require information and training as specified by this provision; of this 20%, half consist of new or replacement (turnover) employees who are assuming new assignments, while the remaining half include existing employees who are receiving new exposures.[7] OSHA estimates that a laboratory supervisor can deliver the required training to 20 employees in a single session, for a total of 16,604 sessions to train 332,082 employees annually (i.e., 332,082 employees ÷ 20 employees per session). In addition, the Agency believes that, for each session, the laboratory supervisor requires 15 minutes (.25 hour) to prepare the training material and 45 minutes (.75 hour) to deliver it, for a total of one hour. Accordingly, the estimated yearly burden hours and cost of this information collection requirement are:

Burden hours: 16,604 sessions x 1 hour = 16,604 hours
Cost: 16,604 hours x $41.29 = $685,579

(D) Medical consultation and medical examinations (§1910.1450(g))

General (§1910.1450(g)(1) and (g)(2))

OSHA believes that 8% (132,833) of the employees covered by the Standard receive medical attention. Of these employees, the Agency assumes that: half (66,417) obtain a medical consultation, which OSHA estimates takes 45 minutes (.75 hour) to administer;[8] one-fourth (33,208) receive a medical examination, which the Agency finds takes 1.5 hours to administer; and the remaining one-fourth get both a medical consultation and medical examination, requiring an estimated total of 2.25 hours to administer. Thus, the estimated annual burden hour and cost to employers of the lost productivity resulting from these provisions are:

Burden hours: (66,417 employees x .75 hour) + (33,208 employees x 1.5 hours) + (33,208 employees x 2.25 hours) = 174,343 hours
Cost: 174,343 hours x $20.21 = $3,523,472

Information provided to the physician (§1910.1450(g)(3))

OSHA estimates that an office clerk spends five minutes (.08 hour) compiling and sending the required information to the physician prior to each medical consultation or medical examination. Therefore, the yearly burden hour and cost estimates for this paperwork requirement are:

7OSHA believes that employers do not repeat this training after the employees have been working in these assignments.

8Estimates of administration time include 30 minutes of travel time.

Burden hours: 132,833 employees x .08 hour = 10,627 hours
Cost: 10,627 hours x $16.95 = $180,128

Physician's written opinion (§1910.1450(g)(4))

The Agency assumes that the physician writes an opinion for each medical consultation and medical examination administered (for a total of 132,833 written opinions annually), and that an office clerk takes five minutes (.08 hour) to distribute the written opinion to an employee.[9] Thus, the estimated burden hours and cost of this requirement each year are:

Burden hours: 132,833 written opinions x .08 hour = 10,627 hours
Cost: 10,627 hours x $16.95 = $180,128

(E) Hazard identification (§1910.1450(h))

OSHA's Hazard Communication (HC) Standard (§ 1910.1200) applies to the requirements regarding labels and MSDSs specified by this provision of the Standard.[10] Therefore, the Agency is accounting for the burden hours and cost resulting from these requirements under the Information Collection Request (ICR) for the HC Standard, OMB Control Number 1218-0072.

(F) Use of respirators (§1910.1450(i))

The Agency accounts for the burden hours and cost resulting from this paragraph (including the selection, use, and maintenance of respirators, and the development of a written respirator protection program) under the Information Collection Request (ICR) for OSHA's Respiratory Protection Standard (§1910.134), OMB Control Number 1218-0099.

(G) Recordkeeping (§1910.1450(j))

General (§1910.1450(j)(1))

As noted above in section (A) ("Exposure Monitoring") of this item, each laboratory facility covered by the Standard develops a record of exposure monitoring results, for an annual total of 45,616 records.[11] In addition, the determinations made above in section (D) ("Medical Consultation and Medical Examinations") show that employers administer 132,833 medical

9The five minutes does not include the annual burden for maintaining a record of each written opinion as required by paragraph (j) of the Standard.

10Paragraph (h)(2)(i) of the Standard requires employers to provide training in accordance with paragraph (f), while paragraphs (h)(2)(ii) mandates CHPs specified by paragraph (e); the Agency included the burden-hour and cost estimates for paragraphs (h)(2)(i) and (h)(2)(ii) in the determinations made under sections (C) and (B), respectively, of this item.

11OSHA assumes that the record is the list of exposure-monitoring results used for posting.

consultations and medical examinations annually, developing 132,833 medical records. Under the requirements of this recordkeeping provision, the Agency estimates that an office clerk spends five minutes (.08 hour) each year establishing and maintaining each of these records. Therefore, the annual burden hours and cost associated with this recordkeeping requirement are:

Burden hours: [(45,616 exposure monitoring records) + (132,833 medical records)] x .08 hour = 14,276 hours
Cost: 14,276 hours x $16.95 = $241,978

Access to records ~~and~~ transfer of records (§1910.1450(j)(2))

The determinations for this provision show that employers spend a total of ~~14,276~~ 14,397 burden hours at a cost of $241,978 providing access to exposure monitoring and medical records to employees, their designated representatives, and OSHA compliance officers, as well as transferring these records to NIOSH as required by paragraph (h) of §1910.1020 ("Access to employee exposure and medical records"). The following sections describe in detail the burden hour and cost determinations for this provision.

1. Employee access

For this determination, OSHA estimates that the exposure monitoring requirements of the Standard cover all employees (1,660,408) in laboratory facilities, while 132,833 of these employees have medical records (see previous determinations in this section). Additionally, the Agency assumes that 10% (179,324) of the employees covered by these records request access to them each year ((1,660,408 employees + 132,833 employees) x 10% = 179,324 employees).[12] OSHA estimates that an office clerk takes five minutes (.08 hour) to retrieve and re-file each requested record, resulting in the following annual burden hour and cost estimates:

Burden hours: 179,324 employees x .08 hours = 14,346 hours
Cost: 14,346 hours x $16.95 = $243,165

2. Federal access

The Agency determined that employers receive 639 requests annually for exposure monitoring and medical records during inspections conducted by its compliance officers (see Item 14 below). In addition, OSHA finds that a laboratory supervisor spends five minutes (.08 hour) informing a compliance officer of the location of the requested records. Accordingly, the estimated yearly burden hours and cost of this provision are:

Burden hours: 639 requests x .08 hours = 51 hours

12The Agency believes that employers receive minimal requests for exposure monitoring and medical records from former employees, employees' legal representatives, individuals and organizations to whom employees give written authorization to exercise a right of access, and designated employee representatives; therefore, it did not include these requests in this determination.

Cost: 51 hours x $41.29 = $2,106

~~Paragraph (h) of § 1910.1020 specifies the conditions for transferring exposure monitoring and medical records to NIOSH. Based on information from the previous ICR, OSHA estimates that four employers will send 333 sets of employee records to NIOSH each year during the period covered by this ICR. The Agency assumes that an office clerk requires one hour to prepare and send a set of records to NIOSH. Therefore, the annual estimated burden hours and cost of this provision are:~~

~~Burden hours: 333 sets of records x 1 hour = 333 hours~~
~~Cost: 333 hours x $16.95 = $5,644~~

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

· The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

· If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondent (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

· Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

Capital Cost Determinations

Annual Medical Cost Determinations

OSHA found that the annual cost of providing employees with exposure monitoring, medical consultations, and medical examinations is $35,978,301. The following sections describe the cost determinations.

(A) Exposure monitoring

The Agency estimates that employers pay $60 to analyze an exposure monitoring sample. According to the information provided above in section (A) ("Exposure Monitoring") under Item 12, employers collect 45,616 exposure monitoring samples each year. Thus, the annual cost associated with obtaining exposure monitoring samples is:

Cost: 45,616 samples x $60 = $2,736,960

(B) Medical consultation and medical examinations

OSHA identified the following costs for providing medical attention to employees: Medical consultation (med consult), $133; medical examination (med exam), $301; and a combined medical consultation and med examination (med consult-med exam), $434.[13] In addition, the determinations made above in section (D) ("Medical consultation and medical examinations") show that each year employers administer 66,417 med consults, 33,208 med exams, and 33,208 med consults-med exams to employees. Accordingly, the yearly cost of providing medical attention to employees is:

Cost: (66,417 med consults x $133) + (33,208 med exams x $301) +
(33,208 med consults-med exams x $434) = $33,241,341

14. Provide estimates of annualized cost of the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff) and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13 and 14 in a single table.

The paperwork requirements specified by the Standard cost the Federal government an estimated ~~$2,055~~ $1,937 each year. The following sections provide the basis for this cost determination.

~~1. Transfer of records~~

~~The determination made above under section (G) ("Recordkeeping") in Item 12 shows that employers send 333 sets of exposure monitoring and medical records to NIOSH annually. The Agency estimates that a NIOSH clerical/secretary (at a wage rate of $19.09 per hour) will spend five minutes (.08 hour) processing each set of records. Therefore, the estimated annual cost of this requirement to the Federal government is:~~

~~Cost: 333 set of records x .08 hour x $19.09 = $509~~

13The previous ICR assumed that each medical consultation cost $125, each medical examination $282, and each combined medical consultation and medical examination $408. The Consumer Price Index (CPI) indicated a 6.6% increase in the price of professional medical services from 2004 to 2006; the cost of a medical consultation or examination was assumed to have increased by 6.6% as well.

~~2.~~ OSHA enforcement

The Agency estimates that a compliance officer (GS-12, step 5), at an hourly wage rate of $37.89, spends five minutes (.08 hour) during an inspection reviewing the documents required by the Standard. OSHA determines that its compliance officers will conduct 606 such inspections during each year covered by this ICR.[14] In making this cost determination, the Agency does not account for other occupational costs (e.g., equipment, overhead, and support staff expenses) because it considers these costs to be normal expenses that would occur without the collection of information requirements specified by the Standard. Thus, the estimated yearly cost of these paperwork requirements to the Federal government is:

Cost: 639 inspections x .08 hour x $37.89 = $1,937

14 [?]The Agency estimated the number of inspections by determining the inspection rate (1.4%) for all facilities under the jurisdiction of the OSH Act (including both Federal OSHA and approved state-plan agencies) and then multiplying the total number of laboratory facilities (i.e., 45,616) by this percentage (i.e., 45,616 facilities x 1.4% = 639 inspections).

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB form 83-1.

OSHA removed the requirement that employers transfer employee exposure-monitoring records and medical records to the National Institute for Occupational Safety and Health in §1910.1020(h)(6), referenced in paragraph §1910.1450(j)(2), under the Standards Improvement Project-Phase III final rule. As a result of this rulemaking, the Agency requests a program change reduction of 333 hours.

In the previous ROCIS entry, OSHA did not update the capital costs, OSHA is adjusting the cost to $35,978,301.

Table 2 below lists the current and requested burden hours of the information collection requirements specified by the Standard, and describes each of the requested burden hour adjustments.

Table 2

Requested Burden Hours and Adjustments

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Estimated Cost ($)	Adjustment	Explanation of Adjustment
A. Employee exposure determination (§1910.1450(d))					
Initial monitoring and periodic monitoring	7,755	7,755	$320,204	0	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
Employee notification of monitoring results	3,649	3,649	$61,851	0	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
B. Chemical hygiene plan (§1910.1450(e))	28,808	28,808	$1,189,482	0	There was an increase in the number of facilities being monitored (from 43,300 to 45,616).
C. Employee information and training (§1910.1450(f))	16,604	16,604	$685,579	0	There was an increase in the number of employees covered by the Standard (from 1,598,385 to 1,660,408) which increased the number of training

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Estimated Cost ($)	Adjustment	Explanation of Adjustment
					sessions (from 15,984 to 16,604).
D. Medical consultation and medical examinations (§1910.1450(g))					
General	174,343	174,343	$3,523,472	0	No change.
Information provided to the physician	10,627	10,627	$180,128	0	No change.
Physician's written opinion	10,627	10,627	$180,128	0	No change.
E. Hazard identification (§1910.1450(h))	0	0	0	0	No change.
F. Use of respirators (§1910.1450(i))	0	0	0	0	No change.
G. Recordkeeping (§1910.1450(j))					
General	14,276	14,276	$241,978	0	No change.
Access to records and transfer of records*	14,730	14,397	~~$250,915~~ $245,271	-333	As a result of the SIP-III Final, OSHA has removed the burden hours on the transfer of records.
Totals	**281,419**	**281,086**	**~~$6,633,737~~ $6,628,093**	**-333**	

***Indicates revision to 29 CFR part 1910.1450(j)(2) calculations to remove the requirements that employers transfer employee exposure - monitoring and medical records to the National Institute for Occupational Safety and Health (NIOSH) and for employers to notify NIOSH prior to disposal of such records.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection information, completion of report, publication dates, and other actions.

OSHA will not publish the information collected under the Standard.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be appropriate.

No forms are available for the Agency to display the expiration date.

18. Explain each exception to the certification statement.

OSHA is not requesting an exception to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The supporting statement does not contain any collection of information requirements that employ statistical methods.